

OCT 19 2001

K013135

**510(k) Summary of
Safety and Effectiveness**

This summary of safety and effectiveness information has been prepared in accordance with the requirements of SMDA 1990 and 21 CFR Part 807.92.

Name: Diagnostic Products Corporation
Address: 5700 West 96th Street
Los Angeles, California 90045-5597

Telephone Number: (310) 645-8200
Facsimile Number: (310) 645-9999

Contact Person: Edward M. Levine, Ph.D.
Director of Clinical Affairs

Date of Preparation: September 18, 2001

Device Name

Trade: IMMULITE® 2000 Allergen-Specific IgE

Catalog Number: L2KUN6 (600 tests)

Common: Reagent system for the detection of allergen-specific IgE in human serum.

Classification: Class II device, DGO (21CFR 866.5510)

Manufacturer: Diagnostic Products Corporation
5700 West 96th Street
Los Angeles, CA 90045-5597

**Establishment
Registration #:** DPC Registration number is 2017183

**Substantially Equivalent
Predicate Device:** AlaSTAT® Microplate Allergen-Specific
IgE (K911511)

Description of Device:

IMMULITE 2000 Allergen-Specific IgE is for *in vitro* diagnostic use with the IMMULITE 2000 Automated Immunoassay Analyzer

Intended Use of the Device:

IMMULITE 2000 Allergen-Specific IgE is for *in vitro* diagnostic use with the IMMULITE 2000 Automated Immunoassay Analyzer – for the measurement of allergen-specific IgE in human serum, as an aid in the clinical diagnosis of IgE-mediated allergic disorders.

Summary and Explanation of the Device:

Many allergies are mediated by immunoglobulins of the IgE class. In sensitized individuals suffering from this immediate (atopic or anaphylactic) type of allergy, IgE molecules act as points of contact between the allergen and specialized cells that release histamine and other agents upon exposure to the allergen; this initiates the events which we recognize as allergic reactions. When evaluated in the light of other clinical and laboratory findings, *in vitro* allergen-specific IgE tests can help the physician identify the allergen (or allergens) to which an individual is sensitive.

Performance Equivalence – Technology Comparison:

Diagnostic Products Corporation (DPC) asserts that IMMULITE 2000 Allergen-Specific IgE and mixed allergen panels are substantially equivalent to the AlaSTAT Microplate Allergen-Specific IgE and mixed allergen panels marketed by DPC.

IMMULITE 2000 Allergen-Specific IgE is a solid-phase, two-step, chemiluminescent immunoassay that exploits liquid phase kinetics in a bead format. It represents a significant advance over conventional methods relying on allergens attached to a solid-phase support, such as a paper disk.

The allergens are covalently bound to a soluble polymer/co-polymer matrix, which in turn is labeled with a ligand. The use of an amino-acid co-polymer amplifies the amount of allergen that the matrix can support.

The patient sample and the allergen are simultaneously introduced into the reaction tube, which contains an immobilized anti-ligand, and incubated for approximately 30 minutes at 37°C with intermittent agitation. During this time, allergen-specific IgE in the sample binds to the ligand-labeled allergen, which, in turn, binds to the anti-ligand on the solid phase. Unbound serum is then removed by a centrifugal wash.

An alkaline phosphatase-labeled anti-human IgE antibody is introduced, and the reaction tube is incubated for another 30-minute cycle. The unbound enzyme conjugate is removed by a centrifugal wash.

Substrate is then added, and the reaction tube is incubated for a further 5 minutes. The chemiluminescent substrate, a phosphate ester of adamantyl dioxetane, undergoes hydrolysis in the presence of alkaline phosphatase to yield an unstable intermediate. The continuous production of this intermediate results in sustained emission of light, thus improving precision by providing a window for multiple reading. The bound complex – and thus also the photon output, as measured by the luminometer – is directly related to the amount of endogenous IgE specific for the allergen.

AlaSTAT Microplate Allergen-Specific IgE is an enzyme-labeled immunometric assay, based on liquid allergens, monoclonal antibodies, and separation by ligand-coated wells. AlaSTAT Microplate is unique in the use of allergens in a liquid format. The allergens are covalently bound to a soluble polymer/co-polymer matrix which in turn is labeled with a ligand – the same ligand used for coating the reaction wells. The use of an amino acid co-polymer amplifies the amount of allergen that the matrix can support.

A ligand-labeled allergen and a patient sample are pipetted into ligand-coated wells – either manually or with an automated liquid-handling device – and then incubated for one hour. During this time, any IgE specific for the test allergen binds to it.

Addition of a multivalent anti-ligand creates a bridge between the allergen/IgE complexes and the ligand-coated wells during a second one-hour incubation. Separation of bound from free is then a simple matter of decanting and washing.

The allergen/IgE complexes thus linked to the microtiter well are now reacted with horseradish peroxidase-labeled monoclonal anti-IgE during a third one-hour incubation, after which excess enzyme label is washed away.

A chromogenic substrate reactive with the enzyme label is then added, and the rate of color development is ascertained by monitoring the product using a kinetic microplate analyzer during a 5-minute read at 450nm. Reaction rates – measured in milli-Optical Density units per minute (mOD/min) – are directly related to allergen-specific IgE concentrations.

Conclusion:

The data presented in this summary of safety and effectiveness is the data that the Food and Drug Administration used in granting DPC substantial equivalence for the IMMULITE 2000 Allergen-Specific IgE and mixed allergen panels.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Edward M. Levine, Ph.D.
Director, Clinical Affairs
Diagnostic Products Corporation
5700 West 96th Street
Los Angeles, California 90045

OCT 19 2001

Re: K013135
Trade/Device Name: IMMULITE® 2000 Allergen-Specific IgE
Regulation Number: 21 CFR § 866.5750
Regulation Name: Radioallergosorbent (RAST) Immunological Test System
Regulatory Class: II
Product Code: DHB
Dated: September 18, 2001
Received: September 19, 2001

Dear Dr. Levine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

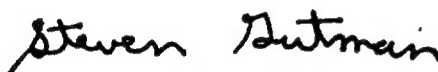
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013135
Device Name: IMMULITE® 2000 Allergen-Specific IgE

Indications For Use: The IMMULITE® 2000 Allergen-Specific IgE is for *in vitro* diagnostic use with the IMMULITE® 2000 Analyzer – for the measurement of allergen-specific IgE in human serum, as an aid in the clinical diagnosis of IgE-mediated allergic disorders.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sanson S. Altare
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013135

Prescription Use
(Per 21 CFR 801.109)

X

OR

Over-The-Counter Use

(Optional Format 1-2-96)